

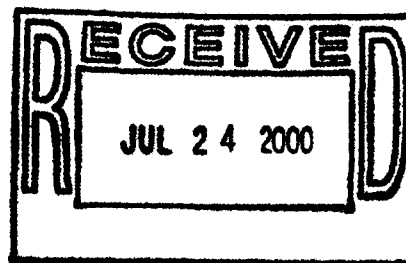


XETAPHARM™
Natural Preventive Healthcare

9753 '00 AUG -8 P2:30

XetaPharm, Inc.
100 Jersey Avenue
Building B, Suite 310
New Brunswick, NJ 08901-3279
(908) 249-0133
Fax (908) 247-4090

July 17, 2000



Dr. Elizabeth A. Yetley, Director
Office for Special Nutritionals, HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, N.W.
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343 (r)(6)) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and in the labeling in connection with the marketing of the dietary supplement Co-Enzyme Q-10, 30 mg Soft Gelatin Capsule. Co-Enzyme Q-10, 30 mg Soft Gelatin Capsule was first marketed with these statements of nutritional support on May 16, 2000. The statements of nutritional support are as follows:

Label:

DIRECTIONS: As a dietary supplement, adults take one soft gelatin capsule daily preferably with or after a meal or as advised by a Health Care Professional.

WARNINGS*:

- KEEP OUT OF REACH OF CHILDREN.
- DO NOT USE IF PREGNANT OR NURSING.
- DO NOT USE IF THE TAMPER-RESISTANT SEALS UNDER THE CAP OR NECKBAND ARE BROKEN OR MISSING.

A Label copy is attached.

975-0162

LET 5705

Dr. Elizabeth A. Yetley, Director
Office of Special Nutritionals
Page 2 , July 17, 2000
Labeling:

XetaPharm™
Natural, Curative and Preventative Healthcare

Introducing
Co-Enzyme Q-10
A Co-Enzyme Q-10 Product in a Convenient 30 mg Dosage

Quality

The purity and potency is laboratory verified by High Performance Liquid Chromatography (HPLC). We assure you the highest quality product. Co-Enzyme Q-10 is an important antioxidant and free radical scavenger*.

Convenience

Provides 30 mg of standardized Co-Enzyme Q-10 in a convenient 30 mg, easy to swallow soft gel capsule.

Value

Co-Enzyme Q-10 is a better value than other leading brands. Know you are buying the best.

Standardized

XetaPharm™ demands that the same rigid standardization must go into developing and manufacturing nutritional supplements as go into pharmaceutical products. We measure quality with only one yard stick. There is consistency and uniformity throughout the product line.

30 mg, Laboratory tested

Co-Enzyme Q-10 Available in 60 capsule bottles

*Ernster L. (1977) Facts and ideas about the function of coenzyme Q10 in the Mitochondria: In: Folkers K., Yamamura Y. (eds) Biomedical and Clinical Aspects of Coenzyme Q. Elsevier, Amsterdam, pp 15-8.

To place an order, or for more information about other XetaPharm products call customer service at: 1-800-858-5854 www.XetaPharm.com

A Labeling copy is attached.

Very truly yours,
XetaPharm, Inc.
A subsidiary of
Xechem, International Inc.



Ramesh Chandra Pandey, Ph.D.
President and CEO

Directions: As a dietary supplement, adults take one soft gelatin capsule daily preferably with or after a meal or as advised by a Health Care Professional.

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- DO NOT USE IF THE TAMPER-RESISTANT SEALS UNDER THE CAP OR NECKBAND ARE BROKEN OR MISSING.



Co-Enzyme Q-10

**30 mg
Dietary Supplement**

See side panel for supplemental facts

60 Soft Gelatin Capsules

XETAPHARM™

Distributed by:
XetaPharm™ Inc.
New Brunswick, New Jersey 08901, USA

Supplement Facts: Serving Size: 1 Soft Gelatin Capsule
Amount Per Soft Gelatin Capsule
% Daily Value

Co-Enzyme Q-10 30 mg

• Daily Value not established
Inert Ingredients: Gelatin, Glycerin, Purified Water, Natural Opacifier, Medium Chain Triglycerides, Annatto Seed Extract, Calcium Hydroxide Concentrate and in a proprietary hydrocolloid base.

Free From: Sugar, starch, yeast, salt, wheat, corn, milk, preservatives, artificial colors and flavors.

To preserve quality and freshness, keep bottle tightly closed. Store in a cool, dry place 68° to 86°F (20° to 30°C).

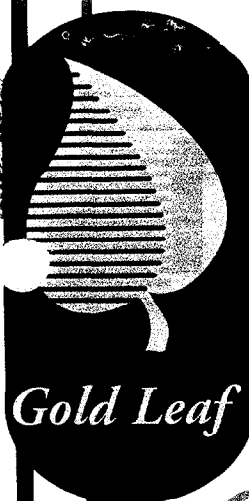


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PROD. # P176

Lot #:

Exp. Date:



XETAPHARM™

Natural, Curative and Preventative Healthcare

Gold Leaf Quality...
Bridging the Gap
Between
Nutraceuticals and
Pharmaceuticals

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